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09/741,426	12/21/2000	V	Akintade Oyedele Dare	MHK-099	5247
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Lawrence Har	bin			EXAM	INER
McIntyre Harbin & King One Massachusetts Avenue, N.W., Suite 330			GOLDBERG, JEANINE ANNE		
Washington, Do				ART UNIT	PAPER NUMBER
				1634	
				DATE MAILED: 01/21/2002	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)		
		09/741,426	DARE, AKINTADE OYE	DELE	
	Office Action Summary	Examiner	Art Unit		
		Jeanine A Goldberg	1634		
Period fo	- The MAILING DATE of this communication ap r Reply	pears on the cover sheet wit	n the correspondence address	·	
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status					
1)⊠	Responsive to communication(s) filed on <u>07</u>	January 2003 .			
2a)⊠	This action is FINAL . 2b) T	his action is non-final.			
3) <u></u> ☐	Since this application is in condition for allow closed in accordance with the practice under	rance except for formal mat Ex parte Quayle, 1935 C.D	ters, prosecution as to the me D. 11, 453 O.G. 213.	erits is	
-	on of Claims Claim(s) <u>1-11,14,15 and 18-20</u> is/are pending	n in the application			
	4a) Of the above claim(s) is/are withdra				
	Claim(s) is/are allowed.				
•	Claim(s) <u>1-11,14,15, 18-20</u> is/are rejected.				
•	Claim(s) is/are objected to.				
• —	Claim(s) are subject to restriction and/	or election requirement.			
	on Papers				
,	The specification is objected to by the Examin				
10)	The drawing(s) filed on is/are: a)☐ acc				
	Applicant may not request that any objection to t				
11)∐	The proposed drawing correction filed on		isapproved by the Examiner.		
40\U-	If approved, corrected drawings are required in r				
• • •	The oath or declaration is objected to by the E	.Aaiiiiiibi .			
Priority under 35 U.S.C. §§ 119 and 120					
	13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).				
a)	a) All b) Some * c) None of:				
	1. Certified copies of the priority documents have been received.				
	2. Certified copies of the priority documents have been received in Application No				
* (3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
14) 🗌 /	14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).				
 a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. 					
Attachmer					
2) Notice	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of	Summary (PTO-413) Paper No(s) Informal Patent Application (PTO-15		

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DETAILED ACTION

- 1. This action is in response to the papers filed January 7, 2003. Currently, claims 1-11, 14,15,18 and 19 are pending.
- 2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
- 3. Any objections and rejections not reiterated below are hereby <u>withdrawn</u> in view of amendments to the claims or applicant's arguments.
- 4. The finality of the Office action mailed December 3. 2002 is hereby withdrawn in view of the new ground of rejection set forth below. It is noted, however, that this action is made FINAL. It is noted that the rejections below could have been appropriately made final in the previous office action based upon the amendments to the claims which required the additional reference. The same reference has been used, however, a new date of publication was determined.

Response to Arguments and Declaration

5. The declaration filed January 7, 2003 has been thoroughly considered, but found unpersuasive in view of the new priority date for the Pierce Instructions for Reacti-Bind DNA Coating Solution. Upon further review, the examiner determined that the information was available on February 1997. It is noted that a declaration may not overcome the instant rejections since the reference was available more than a year prior to the filing date.

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Therefore, the new grounds of rejection, based upon the new date of availability, are provided below.

Priority

6. This application claims priority to provisional application 60/171,309, filed December 21, 1999.

It is noted that the examiner could not find basis for the claims in the provisional application. However, the examiner invites the applicant to point to support, in the event applicant believes that the application should receive benefit of the December 21, 1999 date.

Response to Arguments

Upon further reconsideration and suggestion by the response, the examiner believes that the provisional application supports the concept of mixing the DNA and the Reactibind prior to contacting with the solid support, plate. Thus, the claims receive benefit of the December 21, 1999 filing date.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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7. Claims 1, 3, 5-9, 14-15, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubo et al (Biochemistry, Vol. 31, pages 3703-3708, 1992) in view of Pierce Instructions (Product Description Number 17250, **February 1997**).

Kubo et al (herein referred to as Kubo) teaches a "novel, sensitive, and specific assay for abasic sites, the most commonly produced DNA lesion". Kubo teaches the use of a biotin-tagged reagent specific for the aldehyde groups, called Aldehyde Reactive Probe (ARP). Kubo teaches that "after modification of the aldehyde group with ARP, the biotin-tagged Ap site can then be easily quantitated by the use of avidin/biotin complex technology in an ELISA-like microtiter plate assay" (page 3703, col 2). Kubo teaches a method of binding to an analysis plate (Immulon I microtiter plates) both sample DNA and control DNA (calf thymus DNA containing AP sites) having known abasic sites (page 3704, col 2). The plates were then washed and ARP reagent was added. Unbound ARP reagent was removed by washing with PBS-Tween (page 3704, col 2). Finally, ABC was added to each well, washed and horseradish peroxidase substrate was added and the color development was stopped after an appropriate time (limitations of Claim 6). Absorbance at 490 nm was taken and standard curves were determined with either f1 or calf thymus DNA containing known amounts of AP sites (limitations of Claims 1 and 3). Table 1 illustrates the specificity of the ARP reagent and illustrates that the absorbance is greater with the greater number of AP sites. Kubo clearly teaches "microtiter plates coated with calf thymus DNA containing each of these lesions were incubated with the ARP reagent, and the mount of biotin bound in each of

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the wells was measured by enzyme assay using the avidin/biotin complex (ABS) conjugated with horseradish peroxidase" (Page 3705, col 1).

With respect to Claims 8-9, 14-15, Kubo teaches an additional method for determining the number of intermediary AP sites produced by the action of endonuclease III. The method comprised using 200 ul of calf thymus DNA containing different amount of thymine glycol which was added to each of the wells of a microtiter plate, incubated and washed. Then endonuclease III was added and the plates were incubated. The reaction was terminated and ARP reagent was added and the number of AP sites was determined. The results are illustrated in Figure 4. The ARP assay is rapid, simple, specific and sensitive and offers the possibility of processing a large number of DNA samples through automation.

Kubo does not specifically teach mixing Reacti-Bind DNA coating solution with the nucleic acid prior to contacting with the solid support.

However, Pierce provides the instructions for Reacti-Bind DNA coating solution. Pierce teaches that "utilizing avidin precoated surfaces has the disadvantage that it requires biotinylation of the DNA." Pierce teaches Reacti-Bind DNA coating solution is a quick and cost effective method of immobilizing DNA onto plastic surfaces.

Therefore, it would have been prima facie obvious for the ordinary artisan to have modified the method of Kubo which teaches using an avidin/biotin complex to attach nucleic acids to the solid support with the teachings of Pierce. Since Pierce specifically teaches that the use of Reacti-Bind DNA coating solution is preferable over biotin/avidin precoated surfaces, the ordinary artisan would have been motivated to have used the

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Reacti-Bind DNA coating to immoblize DNA onto plastic surfaces for the explicit benefits of Pierce, namely quick, simple and cost effective.

8. Claims 1, 3, 5-7, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ide et al (Biochemistry, Vol 32, pages 8276-8283, 1993)in view of Pierce Instructions (Product Description Number 17250, **February 1997**).

Ide et al (herein referred to as Ide) teaches a method for detection of aabasic sites in DNA. Ide teaches that the aldehyde group in an aabasic site is first modified by a probe bearing biotin residue, call the Aldehyde Reactive Probe (ARP) and then the tagged biotin is quantified in an ELISA-like assay (abstract). Ide teaches that aabasic sites are common lesions in DNA and are considered to be important intermediates in mutagenesis and carcinogenesis. Ide teaches preparing DNA with abasic sites by treating calf thymus DNA. Duration of the heat treatment varied to introduce different amounts of abasic sites into DNA (page 8278, col 2). Ide also teaches sampling DNA from HeLa RC355 cells and subjecting the DNA to the ARP assay. The microtiter plates were incubated with 200 uL of DNA solution in each well. The plates were washed and ARP solution was added and allowed to incubate. Then ABC solution was added followed by enzyme substrate solution, ABTS, and finally subjected to OD measurement at 405 nm (page 8279, col 1).

Ide does not specifically teach mixing Reacti-Bind DNA coating solution with the nucleic acid prior to contacting with the solid support.

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However, Pierce provides the instructions for Reacti-Bind DNA coating solution. Pierce teaches that "utilizing avidin precoated surfaces has the disadvantage that it requires biotinylation of the DNA." Pierce teaches Reacti-Bind DNA coating solution is a quick and cost effective method of immobilizing DNA onto plastic surfaces.

Therefore, it would have been prima facie obvious for the ordinary artisan to have modified the method of Ide which teaches using an avidin/biotin complex to attach nucleic acids to the solid support with the teachings of Pierce. Since Pierce specifically teaches that the use of Reacti-Bind DNA coating solution is preferable over biotin/avidin precoated surfaces, the ordinary artisan would have been motivated to have used the Reacti-Bind DNA coating to immoblize DNA onto plastic surfaces for the explicit benefits of Pierce, namely quick, simple and cost effective.

9. Claims 1-3, 5-7, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makrigiorgos (US Pat. 6,174,680, January 2001) in view of Pierce Instructions (Product Description Number 17250, **February 1997**).

Makrigiorgos teaches a method of assaying for aabasic sites by using FARP (fluorescent aldehyde reactive probe). Makrigiorgos teaches that for chemiluminescence studies, Reacti-Bind NeutrAvidin coated polystyrene plates are used (col 22, lines 65-67)(limitations of Claim 5). Makrigiorgo teaches FARP-trapping of aldehydes and subsequent DNA biotinylation which includes incubated FARP with DNA, removing the non-covalently bound FARP, and subsequently immobilized the FARP-labeled DNA on microplates and then analyzed in chemiluminescent studies. In section

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4, col 23, Makrigiorgos teaches chemiluminescence measurement of FARP-trapped aldehydes in calf thymus or plasmid DNA by immobilizing the dsDNA on microplates and analyzed (col 23, lines 50-65).

Makrigiorgos does not specifically teach mixing Reacti-Bind DNA coating solution with the nucleic acid prior to contacting with the solid support.

However, Pierce provides the instructions for Reacti-Bind DNA coating solution. Pierce teaches that "utilizing avidin precoated surfaces has the disadvantage that it requires biotinylation of the DNA." Pierce teaches Reacti-Bind DNA coating solution is a quick and cost effective method of immobilizing DNA onto plastic surfaces.

Therefore, it would have been prima facie obvious for the ordinary artisan to have modified the method of Makrigiorgos which teaches using Reacti Bind NeutrAvidin coated plates to attach nucleic acids to the solid support with the teachings of Pierce. Since Pierce teaches that the use of Reacti-Bind DNA coating solution allows the immobilization of DNA onto plastic surfaces, the ordinary artisan would have been motivated to have used the Reacti-Bind DNA coating solution to immobilize DNA onto plastic surfaces for the explicit benefits of Pierce, namely quick, simple and cost effective. The ordinary artisan would have recognized that mixing the Reacti Bind solution with DNA prior to contacting the nucleic acid with the solid support or using the coated plates would facilitate the same intended use of ease of immobilizing DNA.

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10. Claims 1-3, 5-11, 14-15, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubo et al (Biochemistry, Vol. 31, pages 3703-3708, 1992) in view of Pierce Instructions (Product Description Number 17250, **February 1997**) and further in view of Nakamura et al. (Cancer Research, Vol. 58, pages 222-225, January 1998) or Makrigiorgos (US Pat. 6,174,680, January 2001).

Kubo et al (herein referred to as Kubo) teaches a "novel, sensitive, and specific assay for aabasic sites, the most commonly produced DNA lesion". Kubo teaches the use of a biotin-tagged reagent specific for the aldehyde groups, called Aldehyde Reactive Probe (ARP). Kubo teaches that "after modification of the aldehyde group with ARP, the biotin-tagged Ap site can then be easily quantitated by the use of avidin/biotin complex technology in an ELISA-like microtiter plate assay" (page 3703, col 2). Kubo teaches a method of binding to an analysis plate (Immulon I microtiter plates) both sample DNA and control DNA (calf thymus DNA containing AP sites) having known aabasic sites (page 3704, col 2). The plates were then washed and ARP reagent was added. Unbound ARP reagent was removed by washing with PBS-Tween (page 3704, col 2). Finally, ABC was added to each well, washed and horseradish peroxidase substrate was added and the color development was stopped after an appropriate time (limitations of Claim 6). Absorbance at 490 nm was taken and standard curves were determined with either f1 or calf thymus DNA containing known amounts of AP sites (limitations of Claims 1 and 3). Table 1 illustrates the specificity of the ARP reagent and illustrates that the absorbance is greater with the greater number of AP sites. Kubo clearly teaches "microtiter plates coated with calf thymus DNA containing each of these

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lesions were incubated with the ARP reagent, and the mount of biotin bound in each of the wells was measured by enzyme assay using the avidin/biotin complex (ABS) conjugated with horseradish peroxidase" (Page 3705, col 1). With respect to Claims 8-9, 14-15, Kubo teaches an additional method for determining the number of intermediary AP sites produced by the action of endonuclease III. The method comprised using 200 ul of calf thymus DNA containing different amount of thymine glycol which was added to each of the wells of a microtiter plate, incubated and washed. Then endonuclease III was added and the plates were incubated. The reaction was terminated and ARP reagent was added and the number of AP sites was determined. The results are illustrated in Figure 4. The ARP assay is rapid, simple, specific and sensitive and offers the possibility of processing a large number of DNA samples through automation.

Kubo does not specifically teaches a method wherein the sample and control DNA are tagged or labeled with ARP reagent prior to being bound to the analysis plate for comparison. Kubo does not specifically teach mixing Reacti-Bind DNA coating solution with the nucleic acid prior to contacting with the solid support.

However, Nakamura teaches a method of detecting AP sites using an aldehyde reactive probe-slot-blot assay. The method of Nakamura, to measure AP sites, incubates DNA with ARP prior to any immobilization to a solid support. Nakamura then heat denatures the DNA and immobilizes the single-stranded DNA on a BAS-85 NC membrane.

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Additionally, Makrigiorgos teaches a method of using FARP, (fluorescent aldehyde reactive probe). Makrigiorgos teaches FARP-trapping of aldehydes and subsequent DNA biotinylation which includes incubated FARP with DNA, removing the non-covalently bound FARP, and subsequently immobilizing the FARP-labeled DNA on microplates and then analyzed in chemiluminescent studies. Makrigiorgos teaches chemiluminescence measurement of FARP-trapped aldehydes in calf thymus or plasmid DNA by immobilizing the dsDNA on microplates and analyzed (col 23, lines 50-65).

Pierce provides the instructions for Reacti-Bind DNA coating solution. Pierce teaches that "utilizing avidin precoated surfaces has the disadvantage that it requires biotinylation of the DNA." Pierce teaches Reacti-Bind DNA coating solution is a quick and cost effective method of immobilizing DNA onto plastic surfaces.

Therefore, it would have been prima facie obvious for the ordinary artisan to have modified the method of Kubo which teaches using an avidin/biotin complex to attach nucleic acids to the solid support with the teachings of Pierce. Since Pierce specifically teaches that the use of Reacti-Bind DNA coating solution is preferable over biotin/avidin precoated surfaces, the ordinary artisan would have been motivated to have used the Reacti-Bind DNA coating to immobilize DNA onto plastic surfaces for the explicit benefits of Pierce, namely quick, simple and cost effective. Moreover, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Kubo which teaches immobilizing the DNA to the analysis plate, solid support, prior to contacting the DNA with ARP, with the teachings of

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Nakamura or Makrigiorgos which incubates the ARP with the DNA prior to the immobilizing step. The ordinary artisan would have recognized that a method which contacted the DNA with the ARP prior to binding to a solid support and a method which contacted the DNA with the ARP following binding to a solid support would have been equivalent methods. Both of the methods provide highly sensitive results to determining the number of AP sites in a sample DNA. Since the art teaches methods which illustrate that DNA and ARP may be contacted both prior and following binding to a solid support, the ordinary artisan would have recognized that it is irrelevant whether the DNA and the ARP are contacted prior or following binding to a solid support.

11. Claims 1, 3-9, 14-15, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubo et al (Biochemistry, Vol. 31, pages 3703-3708, 1992) in view of Pierce Instructions (Product Description Number 17250, **February 1997**) and further in view of Nikiforov et al (US Pat. 5,679,524, October 1997) or Wood et al (US Pat. 6,277,570, August 21, 2001).

Kubo et al (herein referred to as Kubo) teaches a "novel, sensitive, and specific assay for aabasic sites, the most commonly produced DNA lesion". Kubo teaches the use of a biotin-tagged reagent specific for the aldehyde groups, called Aldehyde Reactive Probe (ARP). Kubo teaches that "after modification of the aldehyde group with ARP, the biotin-tagged Ap site can then be easily quantitated by the use of avidin/biotin complex technology in an ELISA-like microtiter plate assay" (page 3703, col 2). Kubo teaches a method of binding to an analysis plate (Immulon I microtiter plates) both

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sample DNA and control DNA (calf thymus DNA containing AP sites) having known aabasic sites (page 3704, col 2). The plates were then washed and ARP reagent was added. Unbound ARP reagent was removed by washing with PBS-Tween (page 3704, col 2). Finally, ABC was added to each well, washed and horseradish peroxidase substrate was added and the color development was stopped after an appropriate time (limitations of Claim 6). Absorbance at 490 nm was taken and standard curves were determined with either f1 or calf thymus DNA containing known amounts of AP sites (limitations of Claims 1 and 3). Table 1 illustrates the specificity of the ARP reagent and illustrates that the absorbance is greater with the greater number of AP sites. Kubo clearly teaches "microtiter plates coated with calf thymus DNA containing each of these lesions were incubated with the ARP reagent, and the mount of biotin bound in each of the wells was measured by enzyme assay using the avidin/biotin complex (ABS) conjugated with horseradish peroxidase" (Page 3705, col 1). With respect to Claims 8-9, 14-15, Kubo teaches an additional method for determining the number of intermediary AP sites produced by the action of endonuclease III. The method comprised using 200 ul of calf thymus DNA containing different amount of thymine glycol which was added to each of the wells of a microtiter plate, incubated and washed. Then endonuclease III was added and the plates were incubated. The reaction was terminated and ARP reagent was added and the number of AP sites was determined. The results are illustrated in Figure 4. The ARP assay is rapid, simple, specific and sensitive and offers the possibility of processing a large number of DNA samples through automation.

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Kubo does not specifically teach performing simultaneous assays for the sample DNA and the control DNA so as to remove environmental or process variables at the comparing step. Kubo does not specifically teach mixing Reacti-Bind DNA coating solution with the nucleic acid prior to contacting with the solid support.

However, Nikiforov et al (Nikiforov) teaches that 96-well microtiter dishes used in diagnostic laboratories allow the simultaneous determination of a large number of samples and controls.

Similarly, Wood et al (herein referred to as Wood) teaches the 96 well microtiter plate format allows for simultaneous processing of multiple patient samples. Wood teaches twelve wells are occupied by controls, and samples may be found in the other wells.

Pierce provides the instructions for Reacti-Bind DNA coating solution. Pierce teaches that "utilizing avidin precoated surfaces has the disadvantage that it requires biotinylation of the DNA." Pierce teaches Reacti-Bind DNA coating solution is a quick and cost effective method of immobilizing DNA onto plastic surfaces.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified method of Kubo to use several wells for the control DNA and several wells for the sample DNA as taught by Nikiforov or Wood. The ordinary artisan would have clearly recognized the importance of controls and would have recognized that subjecting the controls to the same conditions as the test samples would have the expected benefit of controlling for variables which may have changed between runs, for example temperature, pressure or other additional

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changes. Further, running controls in the same microtiter plate simultaneously has been used in the art routinely. Nikiforov, in 1994, recognized the importance and benefits of running samples and controls simultaneously. In addition to removing environmental or process variables, which is the concept behind controls, running controls simultaneous with the tests samples provides the expected benefit of reducing time, and materials needed for the assay. The ordinary artisan would have been motivated to have consolidated the experiments taught by Kubo into a single well assay for the benefit of controlling for variations in conditions and processes in addition to the benefit of saving time and reagents. Moreover, it would have been prima facie obvious for the ordinary artisan to have modified the method of Kubo which teaches using an avidin/biotin complex to attach nucleic acids to the solid support with the teachings of Pierce. Since Pierce specifically teaches that the use of Reacti-Bind DNA coating solution is preferable over biotin/avidin precoated surfaces, the ordinary artisan would have been motivated to have used the Reacti-Bind DNA coating to immoblize DNA onto plastic surfaces for the explicit benefits of Pierce, namely quick, simple and cost effective.

Conclusion

- 12. No claims allowable over the art.
- 13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday 7:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg February 13, 2002

> Supervisory Patent Examiner Technology Center 1600